UNITED STATES DISTRICT COURT **EASTERN DISTRICT OF PENNSYLVANIA**

In re: AVANDIA MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION

MDL No. 1871

THIS DOCUMENT RELATES TO:

LLOYD LISCO

٧.

Case No.:

Plaintiffs,

Judge Cynthia M. Rufe

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4714

GlaxoSmithKline, LLC f/k/a SmithKline

Beecham Corp. d/b/a GlaxoSmithKline

Defendant.

COMPLAINT

COMES NOW, the Plaintiff, LLOYD LISCO, by and through the undersigned counsel and hereby sues the Defendant, GlaxoSmithKline, LLC f/k/a SmithKline Beecham Corp. d/b/aGlaxoSmithKline (GLAXOSMITHKLINE herein) and alleges as follows:

- This is a civil action for damages in excess of SEVENTY FIVE THOUSAND DOLLARS 1. (\$75,000.00), the minimal jurisdictional requirement of this court, exclusive of costs and interest.
- This Court has jurisdiction pursuant to 28 U.S.C. § 1332 as there is complete 2. diversity between the parties and the amount in controversy is in excess of \$75,000.00.
- Plaintiff, LLOYD LISCO, began taking Avandia in June, 2004, and took Avandia 3. consistently through February, 2010.
- As a result of taking Avandia, Plaintiff, LLOYD LISCO, suffered pain and injuries 4. including, but not limited to, a myocardial infarction.

- Plaintiff, LLOYD LISCO, is and at all times material to this cause was a resident of
 Orlando, Orange County, Florida.
- 6. Defendant, GLAXOSMITHKLINE ("GSK") is a Delaware corporation at all times material and its principal place of business is in Delaware¹. GLAXOSMITHKLINE ("GSK") was authorized to conduct business in Florida.
- 7. This action arises out of the Defendant's manufacturing, selling, distributing, marketing and/or otherwise promoting Avandia without notice to potential consumers of the potential dangers associated with ingestion of this drug.
- 8. At all times material hereto, GLAXOSMITHKLINE ("GSK") was in the business of developing, manufacturing, selling, distributing, labeling, marketing and/or promoting Avandia for consumer use by prescription.
- 9. Defendant, GLAXOSMITHKLINE ("GSK") did develop, manufacture, design, package, market, sell and distribute this drug in the State of Florida at all times relevant to this action.
- 10. GLAXOSMITHKLINE ("GSK") had control over the design, manufacturing, assembly, labeling, warning, packaging, marketing, advertising, promotion, direct-to consumer advertising, and/or sale of the drug Avandia.
- 11. At all times material, GLAXOSMITHKLINE ("GSK") actually knew of the defective nature of its product, Avandia, yet continued to design, manufacture, market, promote, distribute and sell its product so as to maximize company sales and profits at the expense of consumer safety and health and in conscious disregard of the foreseeable harm caused by Avandia.

¹ On October 27, 2009, SmithKline Beecham Corporation redomiciled from Pennsylvania to Delaware, converted into a limited liability company, and changed its name to GlaxoSmithKline LLC.

- 12. GLAXOSMITHKLINE ("GSK") exhibits such an entire want of care as to establish that its actions were a result of fraud, ill will, recklessness, gross negligence and/or willful and intentional disregard to the plaintiff's rights.
- 13. Although GLAXOSMITHKLINE ("GSK") knew or should have known that dangerous cardiovascular risks were associated with the use of Avandia, it continued on its aggressive marketing campaign and continued to manufacture, package, distribute, promote and sell Avandia without adequate warnings of the serious side effect and risks.
- 14. On June 28, 2010, an article entitled "Rosiglitazone Revisited" was posted on the website for *The Archives of Internal Medicine*. (http://archinte.ama-assn.org/cgi/content/full/2010.207) The article portrays the results of a study conducted by Dr. Steven E. Nissen and Dr. Kathy Wolski, where it was found that Avandia (rosiglitazone) significantly raises a person's risk for cardiac related conditions and suggests an unfavorable benefit to risk ratio regarding same.
- 15. On June 28, 2010, an article entitled "Risk of Acute Myocardial Infarction, Stroke, Heart Failure, and Death in Elderly Medicare Patients Treated With Rosiglitazone or Pioglitazone," was posted on the website for *The Journal of the American Medical Association*. (http://jama.ama-assn.org/cgi/content/full/jama.2010.920) The article portrays the results of a study conducted by Dr. David J. Graham where it was found that the prescription of Avandia (rosiglitazone) was associated with an increased risk of stroke, heart failure, and all-cause mortality and an increased risk of the composite of AMI, stroke, heart failure, or all-cause mortality in patients 65 years or older.

COUNT 1: STRICT LIABILITY AS TO GLAXOSMITHKLINE ("GSK")

16. Plaintiffs adopt by reference all of the General Allegations contained in paragraphs 1 through 15 above, each exclusive, as though fully set forth herein.

- 17. The drug product, Avandia, was defective and unreasonably dangerous when it left the possession of the Defendant manufacturer, GLAXOSMITHKLINE ("GSK") in that:
 - a. When placed in the stream of commerce, Avandia contained unreasonable dangers, designs, and defects, and was not reasonably safe as intended to be used, subjecting plaintiff to risks which exceeded the benefits of the drugs;
 - b. When placed in the stream of commerce, Avandia was defective in design and formulation, making use of the drug more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with plaintiff's conditions;
 - c. Avandia contained insufficient warnings to alert consumers, the consumer's prescribing physicians and users of the severe, life threatening complications and side effects, including but not limited to adverse cardiovascular events.
 - There was misleading advertising and promotion concerning the benefits of using Avandia and;
 - e. There are inadequate post-marketing warnings or instructions because,
 GLAXOSMITHKLINE ("GSK") knew or should have known of the significant
 cardiovascular risks associated with the use of Avandia®. GLAXOSMITHKLINE
 ("GSK") failed to provide adequate warnings to consumers and the consumer's
 prescribing physicians and continued to aggressively promote and advertise
 direct to consumers the sale and use of the drug.
 - 18. Plaintiff, LLOYD LISCO, used Avandia for its intended purpose.
- 19. The drug Avandia was not materially altered or modified prior to use by Plaintiff, LLOYD LISCO.

- 20. Prescribing physicians do not have substantially the same knowledge as manufacturers regarding prescription medication. Prescribing physicians rely on manufacturers to provide adequate and appropriate warnings regarding their products.
- 21. GLAXOSMITHKLINE ("GSK") had a continuing duty to provide accurate and adequate warning to prescribing physicians of the dangers, risks and reactions associated with the use of Avandia.
- 22. The warnings given by GLAXOSMITHKLINE ("GSK") to prescribing physicians regarding Avandia were deficient, inadequate, not accurate, unclear, misleading and/or ambiguous.
- 23. Plaintiff could not have discovered any defects in Avandia through the exercise of due care.
- 24. As a direct and legal result of the defective condition of the drug Avandia, LLOYD LISCO suffered pain and injury including, but not limited to, a myocardial infarction, loss of enjoyment of life, the expense of hospitalization and medical care, and other such expenses

WHEREFORE, Plaintiff, LLOYD LISCO, demands trial by jury of any issue of fact triable of right by a jury, and demands judgment against GLAXOSMITHKLINE ("GSK"), for all allowable damages.

COUNT II: NEGLIGENCE BY GLAXOSMITHKLINE ("GSK")

- 25. Plaintiffs adopt by reference all of the allegations contained in paragraphs 1 through 24 above, each inclusive, as though fully set forth herein.
- 26. At all times material hereto, GLAXOSMITHKLINE ("GSK") had a duty to exercise reasonable care in the design, manufacture, testing, processing, labeling, packaging, advertising, marketing, distribution and sale of its products.
- 27. Defendant, GLAXOSMITHKLINE ("GSK"), knew or should have known that its prescription medication Avandia® caused unreasonably dangerous risks and serious side effects.

Despite its knowledge, GLAXOSMITHKLINE ("GSK"), aggressively advertised, marketed, sold and distributed Avandia, knowing that there were safer methods and products for use with pain and inflammation.

- 28. Defendant was negligent and breached their duty in the following manner:
- a. GLAXOSMITHKLINE ("GSK") failed to adequately and properly test its drug product, Avandia® before placing Avandia on the market.
- b. GLAXOSMITHKLINE ("GSK") failed to adequately, accurately and appropriately warn prescribing physicians of the significant risk of cardiovascular events associated with the use of Avandia.
- c. GLAXOSMITHKLINE ("GSK") concealed the dangerous properties of Avandia in order to increase its market share.
- 29. As a direct and legal result of the defective condition of the drug Avandia, LLOYD LISCO suffered pain and injury including, but not limited to, a myocardial infarction, loss of enjoyment of life, the expense of hospitalization and medical care, and other such expenses.

WHEREFORE, Plaintiff, LLOYD LISCO, demands trial by jury of any issue of fact triable of right by a jury, and demands judgment against GLAXOSMITHKLINE ("GSK"), for all allowable damages.

COUNT III: NEGLIGENT MISREPRESENTATION BY GLAXOSMITHKLINE ("GSK")

- 30. Plaintiffs adopt by reference all of the allegations contained in paragraphs 1 through 29 above, each inclusive, as though fully set forth herein.
- 31. GLAXOSMITHKLINE ("GSK") knew or should have known that its prescription medication, Avandia caused unreasonable dangers, risks and serious side effects.
- 32. Despite its knowledge, GLAXOSMITHKLINE ("GSK") aggressively advertised, marketed, sold and distributed Avandia knowing there were safer methods and products for use with pain and inflammation.

- 33. Defendant negligently misrepresented to the plaintiffs and plaintiff's prescribing physician the safety and effectiveness of the drug Avandia and/or negligently misrepresented material information regarding the drug and/or negligently misrepresented adverse information regarding the safety and effectiveness of the drug Avandia.
- 34. GLAXOSMITHKLINE ("GSK")'s negligent misrepresentations were communicated to plaintiff's prescribing physician with the intent that they reach the plaintiffs and that the effect of such representation would be that prescriptions would be written for the drug consuming public, including plaintiff.
- 35. GLAXOSMITHKLINE ("GSK") misrepresented material and adverse information regarding the safety and effectiveness of its product, Avandia.
- 36. GLAXOSMITHKLINE ("GSK") made these representations and actively concealed adverse information at a time when the defendant knew, or should have known, that their drug product had defects, dangers, and characteristics that were other than what GLAXOSMITHKLINE ("GSK") and its representatives had represented to prescribing physicians or other dispensing entities, the FDA, and the consuming public, including plaintiff.
- 37. The misrepresentations of GLAXOSMITHKLINE ("GSK") were perpetuated directly and/or indirectly by GLAXOSMITHKLINE ("GSK") and its employees, agents and/or other detail persons.
 - 38. The misrepresentations by GLAXOSMITHKLINE ("GSK") constitute a continuing tort.
- 39. Through GLAXOSMITHKLINE ("GSK")'s product inserts, GLAXOSMITHKLINE ("GSK") continued to misrepresent the potential risks and complications associated with the drug both before and after plaintiff Herbert Baker's ingestion of the drug.
- 40. Defendant, GLAXOSMITHKLINE ("GSK"), had a continuing duty to warn plaintiff and/or plaintiff's prescribing physicians in a timely manner about the potential risks and complications associated with Avandia.

- 41. GLAXOSMITHKLINE ("GSK") misrepresented the safety and efficacy of Avandia in its labeling, advertising, product inserts, promotional materials and other marketing efforts.
- 42. As a direct and legal result of the defective condition of the drug Avandia, LLOYD LISCO suffered pain and injury including, but not limited to, a myocardial infarction, loss of enjoyment of life, the expense of hospitalization and medical care, and other such expenses

WHEREFORE, Plaintiff, LLOYD LISCO, demands trial by jury of any issue of fact triable of right by a jury, and demands judgment against GLAXOSMITHKLINE ("GSK"), for all allowable

damages.

Dated this _____ day of September, 2010

Maria D. Tejedor, Esq.

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